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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/544,265	08/02/2005	Joachim Moormann	RO4082US (#90568)	1345

28672 7590 08/23/2007
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CLEVELAND, OH 44114

EXAMINER

LEESER, ERICH A

ART UNIT	PAPER NUMBER
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1624

MAIL DATE	DELIVERY MODE
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08/23/2007

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/544,265

Applicant(s)

MOORMANN ET AL.

Examiner

Erich A. Leaser

Art Unit

1624

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-30 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-5, 9, 18, 22-24 and 30 is/are rejected.
- 7) ☒ Claim(s) 6-8, 10-17, 19-21 and 25-29 is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
- 1) ☒ Certified copies of the priority documents have been received.
 - 2) ☐ Certified copies of the priority documents have been received in Application No. ____.
 - 3) ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO/SB/08)
- Paper No(s)/Mail Date 8/2/05 and 1/3/06.

- 4) ☐ Interview Summary (PTO-413)
- Paper No(s)/Mail Date. ____.
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: ____.

DETAILED ACTION

Claims 1-30 are currently pending and under examination.

Priority

Acknowledgment is made that this application is a 371 of PCT/EP04/00485, filed January 22, 2004, which claims foreign priority under 35 U.S.C. 119 to GERMANY 103 04 141.9, filed on February 3, 2003.

Information Disclosure Statement

The references in the IDS dated August 2, 2005 and January 3, 2006, are made of record.

Claim Rejections - 35 USC § 101

35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 22 and 30 are rejected under 35 U.S.C. 101 because the claimed recitation of a use, without setting forth any steps involved in the process, results in an improper definition of a process, i.e., results in a claim which is not a proper process claim under 35 U.S.C. 101. See for example *Ex parte Dunki*, 153 USPQ 678 (Bd.App. 1967) and *Clinical Products, Ltd. V. Brenner*, 255 F. Supp. 131, 149 USPQ 475 (D.D.C. 1966).

Claim Rejections 35 U.S.C. § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Art Unit: 1624

Claim 1, 9, 18, 22 and 30 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicant regards as the invention. The following apply.

Specifically, claim 1 is rejected because the claim language “2-pyrrolidone is used *in excess* relative to said compound (II).” (Emphasis added). Examiner construed this language to mean that the molar ratio of 2-pyrrolidone is greater than that of compound (II) in the chemical reaction to produce compounds of formula (I). The claim language needs to be amended because “in excess” is relative, ambiguous claim language. Clarification is required.

Claim 9 is rejected if Applicant intends this claim to be independent as it refers back to claim 1. If Applicant intends for claim 9 to be independent, then Applicant needs to amend the reference to claim 1 out of claim 9 and include the structure of compound (1) in the body of claim 9. If Applicant intends 9 to be dependent, then this rejection is moot.

Claim 18 is rejected because since compound (III) is both the starting material and the ending material, it is unclear whether the “free base” is the end product. If so, it should be designated as such since the claim reads “starting from a salt.” Clarification is required. This claim is also rejected because it is an independent claim and although it deals with “compound (III),” the claim does not include a figure or diagram showing the structure of compound (III). Correction is required.

Claims 22 and 30 provides for the use of a compound of formula (I) for producing a compound of formula (III), but, since the claim does not set forth any steps involved in the method/process, it is unclear what method/process applicant is intending to encompass. A claim

Art Unit: 1624

is indefinite where it merely recites a use without any active, positive steps delimiting how this use is actually practiced.

Claim Rejections 35 U.S.C. § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 1-5 and 23-24 are rejected under 35 U.S.C. § 103(a) as being unpatentable over Yadav, et al., *Microwave-assisted Rapid Synthesis of the Cytotoxic Alkaloid Luotonin A*, Tetrahedron Letters, Vol. 43, 1905-07 (2002).

Yadav, et al. teaches making peganone by mixing equal molar ratios of isatoic anhydride and 2-pyrrolidone. Note reactant 1e and product 4e in scheme 2 on page 1906, which only differ from the instant process in having equal molar ratios of isatoic anhydride and 2-pyrrolidone

Art Unit: 1624

whereas the instant process demands that “2-pyrrolidone is used in excess relative to said compound (II).” See claim 1.

Although Yadav, et al. does not teach a motivation for a skilled pharmaceutical chemist to modify the molar ratios of the two reactants relative to one another, it is no longer the law for the obviousness rejection to expressly state such teaching, suggestion or motivation. *KSR Int'l Co. v. Teleflex Inc.*, 82 USPQ2d 1385 (2007). The instant process would have been obvious because “a person of ordinary skill has good reason to pursue the known options within his or her technical grasp. If this leads to the anticipated success, it is likely the product not of innovation but of ordinary skill and common sense.”

Applicant points out the recognized needs or problems in the art on page 4 of the specification, which are hereby incorporated by reference the first of which is “enable yields and degrees of product purity which at least correspond to those of known processes, or which surpass them.” As there are only two reactants in the chemical reaction at issue, isatoic anhydride and 2-pyrrolidone, Examiner has made a finding of a finite number of identified predictable potential solutions to Applicant’s recognized needs or problems in the art, i.e., changing the relative molar ratio of the two reactants.

It would have been obvious to one having ordinary skill in the art at the time that the invention was made to increase the reactants and expect such addition to drive the chemical reaction to the right and thereby increase products. See specification page 5. As such, it is Examiner’s position that changing the molar ratio of the reactants of Yadav, et al. is an obvious modification of Yadav, et al. to one skilled in the art. As such, Examiner has made a finding that

Art Unit: 1624

one of ordinary skill in the art could have pursued the known potential options with a reasonable expectation of success.

Further, claim 4 is rejected because the reference teaches that the reaction should be carried out at 120 degrees Celsius which falls within claim 4's range of 50 to 200 degrees Celsius.

Finally, claim 2 is rejected because although the reference does not expressly speak to the issue of crystallization of the reaction product, one skilled in the art knows that this is an inherent step in any process to isolate the final product.

In addition, Yadav, et al. seems to be advantageous over the instant process as the reaction of Yadav takes 5-8 hours compared to the 50-100 hours at room temperature or 2-3 days at 25 degrees Celsius. More importantly, Yadav, et al. resulted in a yield of 92% compared to 40-55% of the instant process after crystallization (Example 2). As such, Examiner contends that because the instant invention produces a lesser yield than the prior art, Applicant did not accomplish the quoted problem Applicant sought to solve with the present invention.

The same rejection could be made over Späth, et al., *On Derivatives of Peganin and their Ring Homologs. VIII. Communications on Peganin*, Ber. 68, 2221-24 (1935); however, the yield of Späth, et al. for the same reaction of Yadav, et al. is only 24.7%.

Objections

Claims 6-8, 10-17, 19-21 and 25-29 are objected to as being dependent upon rejected independent claims 1 and 18, but would be allowable if rewritten in independent form including all of the limitations of the base claims and any intervening claims.

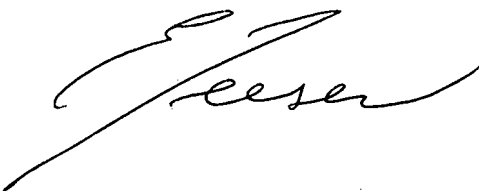
Art Unit: 1624

Conclusion

Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Erich A. Leeser whose telephone number is 571-272-9932. The Examiner can normally be reached Monday through Friday from 8:30 to 6:00 EST.

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Mr. James O. Wilson can be reached at 571-272-0661. The fax number for the organization where this application is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) toll-free at 866-217-9197. If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.



Erich A. Leeser

Patent Examiner, Art Unit 1624

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